CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2006 –7/31/2006

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Recommended Approaches to Integration of Genetic Toxicology Study Results	Pharmacology Toxicology	Level 1	01/04/2006	New
M2: eCTD Specification Questions and Answers and Change Requests	ICH Joint Safety/Efficacy	Level 2	01/06/2006	New
Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice	CGMPs	Level 1	01/12/2006	New
Exploratory Investigational New Drug Studies	Pharmacology Toxicology	Level 1	01/17/2006	New
Investigational New Drugs; Approaches to Complying with Current Good Manufacturing Practice During Phase 1	CGMPs Draft	Level 1	01/17/2006	New
Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling	Level 1	01/24/2006	New
Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling	Level 1	01/24/2006	New
Labeling for Human Prescription Drug and Biological Products — Implementing the New Content and Format Requirements	Labeling Draft	Level 1	01/24/2006	New
Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling Draft	Level 1	01/24/2006	New
Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims	Clinical Medical Draft	Level 1	02/03/2006	New

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Nonclinical Safety Evaluation of Pediatric Drug Products	Pharmacology Toxicology	Level 1	02/15/2006	New
Reports on the Status of Postmarketing Study Commitments – Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997	Procedural	Level 1	02/16/2006	New
Internal Radioactive Contamination – Development of Decorporation Agents	Clinical Medical	Level 1	03/03/2006	New
Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics	Compliance	Level 1	03/14/2006	New
Nonclinical Safety Evaluation of Drug or Biologic Combinations	Pharmacology Toxicology	Level 1	03/15/2006	New
S8: Immunotoxity Studies for Human Pharmaceuticals	ICH Safety	Level 1	04/13/2006	New
Exocrine Pancreatic Insufficiency Drug Products – Submitting New Drug Applications	Clinical Medical	Level 1	04/14/2006	New
Bar Code Labeling Requirements – Questions and Answers	Compliance	Level 1	04/27/2006	New
Q8: Pharmaceutical Development	ICH Quality	Level 1	05/22/2006	New
BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Information	Chemistry	Level 1	06/01/2006	Withdrawn
Drug Product: Chemistry, Manufacturing, and Controls Information	Chemistry	Level 1	06/01/2006	Withdrawn

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Drug Substance: Chemistry, Manufacturing, and Controls Information	Chemistry	Level 1	06/01/2006	Withdrawn
Format and Content of the Chemistry, Manufacturing, and Controls Section of an Application	Chemistry	Level 1	06/01/2006	Withdrawn
Stability Testing of Drug Substances and Drug Products	Chemistry	Level 1	06/01/2006	Withdrawn
Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptides	Chemistry	Level 1	06/01/2006	Withdrawn
Submitting Documentation for the Stability of Human Drugs and Biologics	Chemistry	Level 1	06/01/2006	Withdrawn
Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment	Clinical Medical	Level 1	06/02/2006	New
Q9: Quality Risk Management	ICH Quality	Level 1	06/02/2006	New
Antiviral Product Development – Conducting and Submitting Virology Studies to the Agency	Clinical Antimicrobial	Level 1	06/05/2006	New
Marketed Unapproved Drugs; Compliance Policy Guide	Compliance	Level 1	06/09/2006	New
Useful Written Consumer Medication Information (CMI)	Procedural	Level 1	07/18/2006	New
Q3B(R): Impurities in New Drug Products	ICH Quality	Level 2	07/31/2006	Revised